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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,845	05/29/2001	Chaitan Khosla	300622005500	7453
25225	7590	07/29/2005		
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			EXAMINER ZHOU, SHUBO	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/867,845

Applicant(s)

KHOSLA ET AL.

Examiner

Shubo (Joe) Zhou

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/11/02, 4/12/02, 8/7/02, 6/14/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Amendments***

1. Applicants' election, without traverse, of Group IV (claims 14-17) in the communication filed 11/13/02 is acknowledged. The amendments to the specification filed 11/13/02 are also acknowledged and entered. It is pointed out that applicants are correct in that in the restriction requirement mailed 9/27/02, claims 13-14 were inadvertently included in group II. It is hereby clarified that the invention of group II includes claims 7-12.

Claims 1-17 are currently pending and claims 14-17 are under consideration.

Claims 1-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

2. The preliminary amendment to the specification filed 3/5/02 is not in compliance with 37 CFR 1.121 because no marked-up version of the amendment is provided. In the "Version with Markings to Show Changes Made" filed 3/5/02 (page marked as "sd-79375" at the bottom left corner), there are no actual markings to show changes made.

***Information Disclosure Statement***

3. The Information Disclosure Statements filed 3/11/02, 4/12/02, 8/7/02 and 6/14/04, respectively, have been entered and considered. Initialed copies of the form PTO-1449 are enclosed with this action.

*Specification*

4. The disclosure is objected to because of the following:

4a. The preliminary amendment filed 3/5/02 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is described as follows:

The original specification filed on 5/29/01 on page 1 states: "This disclosure includes a CD appendix." Assuming what is meant by "CD appendix" is an appendix of a compact disc, the disclosure does not indicate what is contained on the CD and no CD was actually included in the application as originally filed on 5/29/01. The preliminary amendment filed 3/5/02, however, amended the specification to recite: "This disclosure includes a computer program listing appendix, containing appendix A, B, and D. Appendix C is submitted herewith as a paper copy, as Figures 6A-6J. The appendices A, B, C and D are incorporated herein by reference." See page 2 of the communication filed 3/5/02. Further, the original disclosure filed 5/29/01 includes only Figures 1-5. The preliminary amendment filed 3/5/02 also amended the specification to recite: "Figures 6A-6AJ [sic] identify the string of PKS modules responsible for production of the compounds. The identity of said modules is shown under the compound names." See also page 2 of the communication filed 3/5/02. The contents on the compact discs in the appendices A, B and D and appendix C containing Figures 6A-6J are new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

4b. The specification contains graphical illustrations on pages 11-13, 15-16, 35, 36, etc. Graphical illustrations, diagrammatic views, flowcharts, and diagrams in the descriptive

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portion of the specification do not come within the purview of 37 CFR 1.58(a), which permits tables, chemical and mathematical formulas in the specification in lieu of formal drawings. The MPEP states that the specification, including any claims, may contain chemical formulas and mathematical equations, but may not contain drawings or flow diagrams. See MPEP 608.01(VI). Note that the illustrations on pages 11-13, 15-16, 35, 36, etc. are not chemical formulas but illustrations of chemical structures. It is requested that such illustrations be provided as formal drawings in accordance with 37 CFR 1.81.

4c. The disclosure is objected to because of the following informalities:

The phrase "This applications [sic] asserts priority to ..." seems contain spelling error. It appears that "This application asserts priority to ..." was intended.

Appropriate correction is required.

### ***Claim Rejections-35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 14-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Consideration of the "Computer-Related Inventions", section 2106 of the MPEP, part IV, revealed that the instant claims are directed to non-statutory subject matter because they manipulate concepts or convert data, but without resulting in any physical transformation outside of the computation or computer. The method steps in claims 14-17 merely define alphanumeric symbol strings representing polyketides, compare the strings with a

database of strings, and generate new strings. They do not result in any physical transformation outside the data manipulation as to the PKS genes to be designed.

***Claim Rejections-35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “said polyketide” recited in step (c), line 8 and step (d), lines 10 and 11 of claim 14, respectively, lacks clear antecedent basis. There is a “desired polyketide” recited in the preamble, and there is a plural “polyketides produced by PKS genes” recited in step (b), line 6 of claim 14. It is not clear which singular “said polypeptide” is meant in step (c), line 8 and step (d), lines 10 and 11. Is it the “desired polyketide” or one of the “polyketides produced by PKS genes?”

The phrase “elements identified in step (b)” recited in claim 14, step (d), line 9, lacks clear antecedent basis. No elements are identified in step (b). Is “elements identified in step (c)” intended?

The meaning of the phrase “wherein all possible PKS genes encoding a desired polyketide from said database are generated and displayed” in claim 15 is not clear. It is unclear whether or not this “desired polyketide” is the same as the “desired polyketide” recited in the preamble of claim 14, from which claim 15 depends. The confusion arises from the use of the indefinite article “a” before the phrase “desired polyketide.”

The phrase "PKS genes encoding a desired polyketide" in claim 15 is confusing. The specification states that polyketides are synthesized by polyketide synthase (PKS) enzymes which are encoded by PKS genes. See page 2 of the specification. Thus, a PKS gene encode a PKS enzyme rather than a polyketide. it is not clear what is meant by "PKS genes encoding a desired polyketide" in the claim.

It is suggested that the full name "polyketide synthase" is spelled out before the acronym "PKS" in the claims given that the acronym "PKS" is also used to stand for genes other than polyketide synthase, such as "protein kinase sequence" recited by McKusick, VA (printed from website <http://srs.sanger.ac.uk/srsbin/cgi-bin/wgetz?%5Bomim-ID:311010%5D+-e>).

### ***Conclusion***

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are

available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.



Patent Examiner

  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**